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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,775	12/28/2001	Richard L. Goode	2401.0268C	6421

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EXAMINER

EASHOO, MARK

ART UNIT PAPER NUMBER

1732

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,775

Applicant(s)

GOODE ET AL.

Examiner

Mark Eashoo, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 28 December 2001 is: a) ☒ approved b) ☐ disapproved by the Examiner
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

The continuation data on page 1, line 1 of the specification is not correct, because parent application 08/427,909 has issued as US Pat. 6,406,453. It is requested that applicant make the appropriate correction to the priority information.

Drawings

The drawing changes filed 28-DEC-2002 are approved by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites "trimming the flange away" which render the claim indefinite because: 1.) such trimming of the flange is not recited in the specification but rather it appears that applicant intended that an "end portion" is separated from the shaft/tube (see pg. 11-12) and 2.) it is unclear if the removed flange is the same as the molded flange and whether or not the final product has a flange attached to the tube.

102 Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Spofford et al. (US Pat. 5,186,168).

Regarding claim 15: Spofford et al. teaches the claimed process of making a medical ventilation tube, comprising: forming a hollow tubular shaft having rigidity and resists bending while in use (18:13-17 and Fig. 22); and molding a flange onto the hollow tubular shaft using a material that has less rigidity than that of a first material in the hollow tubular shaft (18:5-12 and Fig. 22). It is inherent that braided reinforcing material of the hollow tubular shaft has a hardness greater than the soft material of the flange.

Claims 15-17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirsch et al. (US Pat. 080,650).

Regarding claim 15: Hirsch et al. teaches the claimed process of making a medical ventilation tube, comprising: forming a hollow tubular shaft (element 57) having rigidity and resists bending while in use (56:1-6:27 and Fig. 10); and molding a flange (elements 31-32) onto the hollow tubular shaft using a material that has less rigidity than that of a first material in the hollow tubular shaft (4:11-43 and Fig. 1-5). Hirsch et al. teaches that the hollow tubular shaft has a durometer in the range of 30-40 Shore A (6:10-17) and that the flexible connection flange portions have a durometer of 10-40 Shore A (4:31-39). Since the hardness range of the flange extends well below that of the tube, Hirsch et al. meet the instantly claimed limitation directed to material hardness.

Regarding claims 16 and 17: Hirsch et al. teaches attaching the flange to the tube by insert molding (4:55-62). Since the flange surrounds and encompasses the tube, it is inherent that the tube is first placed in the mold and the material forming the flange is then injected into the mold.

Regarding claim 18: Hirsch et al. teaches a flange/second material in the range of 10-40 Shore A (4:30-40), of which the upper portion of this range is "about 50".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al. (US Pat. 080,650).

Hirsch et al. teaches the basic claimed process as set forth above. The rejection below of claim 18 is an alternative rejection, if the 10-40 Shore A range does not inherently teach "about 50".

Regarding claims 18 and 20: Hirsch et al. does not a flange durometer of about 50 or a tube durometer of about 90-95.

Nonetheless, the courts have held that the selection of a known material based upon its suitability for its intended use supports a prima facie case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 65 USPQ 297 (1945). In the present case, Hirsch et al. teaches a range of material hardness suitable for a gastrostomy tube. However, the instant claim is readable upon a variety of medical ventilation tubes having flanges thereon (ie. catheters, antrostomy ventilation tubes, etc.). As such, a person having ordinary skill in the art would have found it obvious to have selected the appropriate material and material hardness for both a tube and flange through routine experimentation and optimization and have utilized such materials because Hirsch et al. suggests that tube must be maintain ventilation and the flange must be flexible enough to prevent premature removal but allow removal when desired while causing minimum trauma to the surrounding tissue.

Regarding claim 19: Hirsch et al. does not teach extruding a tube and cutting the tube to a predetermined length. Nonetheless, extruding a tube and cutting the tube to a predetermined length is well known in the extrusion art. At the time of invention a person having ordinary skill in the art would have found it obvious to have extruded a tube and cutting the tube to a predetermined length, as

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commonly practiced in the art, in the process of Hirsch et al., and would have been motivated to do so in order to provide an economical way of making various lengths of similar diameter tubing by using a single extrusion die instead of numerous closed molds.

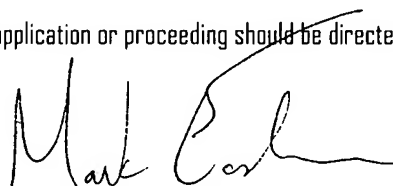
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hakansson and Shikani teach the basic state of the art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Eashoo, Ph.D. whose telephone number is (703) 308-3606. The examiner can normally be reached on 7am-3pm EST, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaanni can be reached on (703) 305-5493. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Mark Eashoo, Ph.D.
Primary Examiner
Art Unit 1732

10/20/03

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